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Guidance for the Reregistration of Pesticide Products Containing Propachlor as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PROPACHLOR: (019101)

EPA CASE NUMBER: 177

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To carry out this task, we have established the Registration Standards program, which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. Based on the regulatory position, the Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing use product producers (basic suppliers of the active ingredient). However, end use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position and rationale of the Environmental Protection Agency ("the Agency") for all registered manufacturing-use products (MUPs) containing propachlor as the sole active ingredient. The Agency bases its position and rationale on an evaluation of all such products and Section 3, 24(c) and intrastate uses registered for propachlor. End-use products (EUPs) are reviewed only when there are no MUPs registered or when the standard imposes requirements of significant changes in the label. Mixtures are included only when there are requirements for significant changes in the label. After briefly describing the chemical and its uses, this chapter presents the regulatory position and rationale, the criteria for registration, acceptable ranges and limits, labeling requirements and the tolerance reassessments.

B. DESCRIPTION OF CHEMICAL

Propachlor is the accepted common name for the compound: 2-Chloro-N-isopropylacetanilide as determined by the British Standards Institution, International Organization for Standardization, and the Weed Science Society of America. Propachlor is marketed under the trade name Ramrod®, and other names such as: Bexton® and CP 31393®. The Chemical Abstracts Service (CAS) Registry number is 1918-16-7. The Office of Pesticide Programs' EPA Chemical Code Number is 019101.

Propachlor is a light tan solid at room temperature and has a pungent odor. The empirical formula is $C_{11}H_{14}ClNO$, and its molecular weight is 211.70. The boiling point is 110°C at 0.3 mm Hg. Propachlor is soluble in most organic solvents and in water (at 23°C) to 693 ppm.

Propachlor is registered for use as a selective preemergence alpha-chloroacetamide type herbicide for the control of germinating annual grasses and broadleafed weeds. Propachlor is mainly applied as a preemergence broadcast spray or banded ground application, and only one application is allowed per year. In addition, aerial application of propachlor is allowed. Propachlor is absorbed mainly by germinating shoots, then is translocated throughout the plant and accumulates in the vegetative parts where it acts by inhibiting protein synthesis.

Propachlor was patented by the Monsanto Chemical Company (US Patent No. 2,863,752) in 1958 and was first registered for use in 1965. Technical propachlor is being produced in the United States by Monsanto Agricultural Products Company of St. Louis, Missouri.

Propachlor is available as a technical material, at 93.0 % active ingredient for formulation of propachlor end-use products. Propachlor is available in granular, wettable powder, and flowable liquid concentrate formulations.

C. REGULATORY POSITION AND RATIONALE

Based on the review and evaluation of all available data and other relevant information on propachlor, the Agency has made the following determinations:

1. The available data are insufficient to show that any of the risk criteria listed in § 162.11(a) of Title 40 of the U.S.Code of Federal Regulations have been met or exceeded for the uses of propachlor at the present time.

   Rationale: There are no valid long term chronic toxicity data for propachlor. Studies indicate that propachlor is structurally similar to alachlor which is oncogenic in laboratory rats and mice. Data on propachlor show that it is corrosive to the eye with corneal opacity irreversible after 7 days. Further, Propachlor has been shown to be highly toxic to coldwater fish, highly to moderately toxic to warm-water fish and highly to moderately toxic to freshwater invertebrates. In addition to the extensive subchronic and chronic toxicity data gaps, there are also residue chemistry and environmental fate data gaps. Because the existing data are insufficient to show that any of the risk criteria have been met or exceeded, the Agency is not initiating a Special Review at this time.

   The most appropriate regulatory action is to move quickly to fill the data gaps. Then the Agency will make a determination as to the future registerability of the affected uses.

2. MUPs and EUPs containing propachlor must bear Toxicity Category I hazard statements. In addition, all EUPs must bear label statements requiring mixers, loaders, and applicators to use protective clothing and equipment. Registrants must revise the labeling of MUPs and EUPs as specified in the "Required Labeling" section on products released for shipment as of September 1, 1985.

   Rationale: Primary eye irritation data on propachlor reviewed by the Agency show corrosivity and corneal opacity not reversible within seven days in rabbits. If propachlor came in contact with the eyes, it could cause irreversible eye injury to man. Propachlor may also induce photosensitivity or photosensitization due to the presence of aniline in its composition.

3. The Agency will prohibit the aerial application of propachlor and require a statement on the label of products containing propachlor stating that aerial application is not permitted.

   Rationale: The Agency is concerned about exposure to non-target species as a result of increased drift (over ground application) from aerial application. Drift from the site of application could result in the following:

   a. Irreversible eye damage to man and possibly photosensitivity or photosensitization due to the presence of aniline in propachlor's composition.

b. Acute toxicity to coldwater fish, warmwater fish and to fresh-invertebrates.

Further, aerial application of propachlor is currently a minor method of application and the prohibition of aerial application would most likely have a minimal economic impact on the farming community.

4. The Agency is requiring critical product chemistry, environmental fate and chronic toxicity data on propachlor as soon as possible. Once the Agency has evaluated these additional data, it will determine if EPA should initiate the Special Review process.

Rationale: The Agency has identified the following potential adverse effects on man:

a. Propachlor is structurally similar to alachlor which is oncogenic in laboratory rats and mice,

b. There is a high probability that propachlor will contaminate ground water because of its solubility and mobility in sandy soils low in organic matter.

5. The Agency will not approve any new uses (Section 3) or 24(c) registrations for propachlor until data have been received and reviewed.

Rationale: Extensive data gaps exist in the areas of chronic toxicity subchronic toxicity; environmental fate; and residue chemistry for propachlor. Until the Agency receives and reviews the data required in this guidance package, it cannot fully assess the potential hazards of increased and/or new uses of propachlor.

6. The Agency will consider a Section 18 exemption for propachlor on a case-by-case basis.

Rationale: Emergency exemption to use propachlor by a Federal or State agency will only be granted after stringent review of each pest outbreak shows that the temporary application of propachlor will not cause adverse effects to non-target species and the ecosystem.

7. The Agency will not grant any pending or new tolerances for propachlor until data have been received and reviewed. Then the Agency can determine whether the new data support the tolerances.

Rationale: While the current TMRC utilizes only 5.26% of the ADI, a full tolerance reassessment has not been completed by the Agency, because of certain residue chemistry and toxicity data gaps. In order to review tolerances, the Agency is requiring data to fill existing gaps.

8. New and /or amended environmental hazard precautions are being imposed for MUPs and EUPs to reflect the chemical's potential adverse effects to non-target organisms. (Refer to Section F. REQUIRED LABELING)

Rationale: The data base for acute aquatic toxicity shows that propachlor is highly toxic to coldwater fish, highly to moderately toxic to warmwater fish and highly to moderately toxic to freshwater invertebrates. However, due to gaps in environmental fate data, the Agency cannot adequately assess this chemical's effects on aquatic species' populations.

While a Special Review is not warranted at this time, the Agency is imposing warning statements on MUP and EUP labels to reduce the hazards to non-target organisms, until such time as the necessary data are received and reviewed.

Regarding the potential effects on endangered species, the Agency is not taking any specific action under this document. Rather, the Agency is pursuing this matter under a "cluster approach" with other pesticides of similar uses. After reviewing the cluster, the Agency plans to notify (By early 1986) the states' agricultural extension offices of endangered species labeling restrictions and precautions. Then these offices will provide appropriate notification to the users of propachlor.

9. Available data are insufficient to fully assess the environmental fate of propachlor and the exposure of humans and other non-target organisms to propachlor.

Rationale: In the ecosystem, propachlor is adsorbed by soil colloids. Microbes are the primary factor in the breakdown of propachlor in soils. It's loss from photodecomposition and/or volatilization are low. Propachlor's solubility rate is high and it is very mobile in sandy soils low in organic matter.

However, environmental fate data gaps exist for propachlor in degradation, photodegradation, soil dissipation, rotational crops (confined), fish accumulation and are only partially filled for aerobic soil metabolism and leaching data requirements.

10. The Agency has designated for further study, certain chemicals including propachlor which may have a potential to enter ground water supplies in the U.S. based on such factors as chemical structures, solubility and use patterns. Propachlor was included in the May 1984, Data Call-In for ground water. Nontheless, the Agency is requiring additional data to evaluate propachlor's potential to contaminate ground water.

Rationale: There is a high probability that propachlor will contaminate ground water because of its solubility and mobility in sandy soils low in organic matter. The Agency requires the following fate data: hydrolysis (§161-1), photodegradation (§161-2, 161-3), soil metabolism (§ 162-1, 162-2), mobility (§163-1), and field dissipation (§164-1). Until such data are submitted and evaluated, EPA cannot assess propachlor's potential to contaminate ground water. Data were submitted recently by a registrant in response to the May 1984 Data Call-In Notice. They were reviewed by the Agency and were declared insufficient in meeting ground water data requirements.

11. The Agency is not requiring a reentry interval for currently registered uses at this time.

Rationale: While this chemical is in Toxicity Category I on the basis of corrosivity and corneal opacity, The Agency is not requiring a reentry interval at this time. Propachlor is mainly applied as a preemergence broadcast spray or banded soil application and not applied as a foliar spray. Only one application is allowed per year. Because of the application methods used for propachlor, it is unlikely that workers would be in the field 24 hours after the application of the pesticide.

12. Manufacturing-use pesticide products containing propachlor as a sole active ingredient may be registered for sale, distribution, formulation and use in the United States, subject to the terms and conditions specified in this document.

Rationale: Registrants must provide and agree to develop additional data, as specified in the tables of this guidance document, to maintain existing registrations.

D. CRITERIA FOR REGISTRATION UNDER THIS DOCUMENT

To be subject to this guidance document, manufacturing-use products must meet the following conditions:

1. Contain propachlor as the sole active ingredient and,
2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section E of this document.

Registration of products subject to this document must comply with all terms and conditions described in it, including commitment to fill data gaps on a schedule acceptable to EPA and consistent with that required of the present registrant. All registrants and applicants for registration under this document must follow the instructions contained in this document and complete and submit the appropriate forms within the specified time.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 93.0 percent propachlor as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use propachlor products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registerable under this guidance document.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing propachlor, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registrable under this Standard, manufacturing-use products containing propachlor must be labeled for formulation only into end-use products only for the commodities listed below. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

Propachlor is registered for use as a preemergence herbicide on corn (all types), soybeans (seed only), grain sorghum (milo), green peas, pumpkins, cotton and flax. In corn, propachlor can also be applied as an early postemergence control. Grain sorghum is the largest use site for propachlor. Corn is the second largest use site for propachlor.

F. REQUIRED LABELING

All technical grade, MUPs, and EUPs containing propachlor must bear appropriate labeling as specified in 40 CFR § 162.10. Other portions of this guidance package contain specific information regarding label requirements.

In addition to the requirements stated in 40 CFR § 162.10, the following information must appear on the labeling:

1. Manufacturing-Use Product Statements

All products intended for formulation into end-use products must bear the following statement:

"DANGER. Corrosive, causes irreversible eye damage. Harmful if swallowed or absorbed. Do not get in eyes or on clothing. Wear goggles, face shield or safety glasses".

"Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency".

2. End-Use Product Statements

The following human hazard statement must appear on all EUP labels:

"DANGER. Corrosive, causes irreversible eye damage. Harmful if swallowed or absorbed. Do not get in eyes or on clothing".

a. Granular Products

The following environmental hazard statement must appear on all granular EUP products:

"This pesticide is toxic to fish. Do not apply directly to water. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. In case of spills, collect for use or properly dispose of granules".

b. Non Granular Products

The following environmental hazard statement must appear on all non granular EUP products:

"This pesticide is toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes. In case of spills, collect for proper disposal".

c. The following precautionary statements must appear on all EUP products:

"Required clothing and equipment for mixing/loading and applying propachlor":

"One-piece coveralls which have long sleeves and long pants constructed of laminated fabric as specified in the USDA/EPA Guide for Commercial Applicators".

"Goggles, face shield, or safety glasses".

"Liquid-proof hat such as a plastic hard hat with a plastic sweat band".

"Heavy-duty liquid proof rubber (neoprene) work gloves".

"Any article worn while handling propachlor must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide from any significant spill must be disposed of in a sanitary landfill, by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke".

"Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply".

Prohibition on Aerial Application

"Do not apply with aerial equipment".

G. TOLERANCE REASSESSMENT

EPA's assessment of the Acceptable Daily Intake (ADI) for propachlor used a 90 day feeding study on rats, with a No-Observable-Effect-Level (NOEL) of 13.3 mg/kg or 266.00 ppm. A 2,000-fold safety factor was used and the ADI was calculated as 0.0067 mg/kg/day with a Maximum Permissible Intake (MPI) of 0.3990 mg/day for a 60 kg person. The current Theoretical Maximum Residue Contribution (TMRC) for propachlor, based on established tolerances, is 0.0210 mg/day for a 1.5 kg diet. The percentage of the ADI utilized is 5.26%.

The Agency is unable to complete a full tolerance reassessment because the available propachlor residue data do not currently support the established tolerances listed below. Data on the metabolism of residues in plants and animals, and on residue storage stability are required. The additional data will be used to more fully assess dietary exposure to propachlor and may lead to revisions in the existing tolerances. Therefore, the Agency will not grant any pending or new tolerances for propachlor until the required data are submitted.

In the United States, tolerances are currently established in 40 CFR § 180.211 for the combined residues of the herbicide (2-Chloro-N-isopropylacetanilide) and its metabolites (calculated as 2-Chloro-N-isopropylacetanilide) in or on the raw agricultural commodities listed below:

Commodities	Parts per million
Beets, sugar, roots	0.2
Beets, sugar, tops	1.0
Cattle, fat	0.02
Cattle, meat by-products	0.02
Cattle, meat	0.02
Corn, forage	1.5
Corn, fresh, (sweet)(K+CWHR)	0.1
Corn, grain	0.1
Cottonseed	0.1
Eggs	0.02
Flax, seed	3.0
Flax, straw	10.0
Goats, fat	0.02
Goats, meat by-products	0.02
Goats, meat	0.02
Hogs, fat	0.02
Hogs, meat by-products	0.02
Hogs, meat	0.02
Horses, fat	0.02
Horses, meat by-products	0.02
Horses, meat	0.02
Milk	0.02
Peas, pods removed	0.2
Peas, forage	1.5

Poultry, fat	0.02
Poultry, meat by-products	0.02
Poultry, meat	0.02
Pumpkins	0.1
Sheep, fat	0.02
Sheep, meat by-products	0.02
Sheep, meat	0.02
Sorghum, fodder	5.0
Sorghum, forage	5.0
Sorghum, grain(milo)	0.25

International Tolerances

Presently, there are no tolerances for residues of propachlor in Canada, Mexico, or in the Codex Alimentarius.

2-CHLORO-N-ISOPROPYLACETANILIDE*

TYPE PESTICIDE: Herbicide

FORMULATIONS:

Tech	(93%)
G	(8.3%, 10%, 13.34%, 18%, 20%, 25%, 26.5%)
WP	(30%, 39%, 48.1%, 65%)
EC	(2 lb/gal)
F1C	(3 lb/gal, 4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: A preemergence, selective, soil active herbicide. Soil surface should be freshly worked and free of weed top growth. Some moisture, as either rain or irrigation, is required soon after application. Harrowing or rotary hoeing after application may reduce weed control. Use the lower dosages for sandy soils, the medium dosages for silt loam soils, and the higher dosages for clay soils or in areas of heavy weed infestation. Reudce dosages in proportion to band area actually treated.

Livestock Tolerances: 0.02 ppm (negligible residue) in eggs, milk, meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Malformed growth and severe inhibition of emerging shoots of weeds.

PHYTOTOXICITY TO CROPS: Corn - leafing out underground and failure of leaves to unfurl; soybeans - leaves crinkle and form a heart-shaped appearance.

MODE OF ACTION: Inhibits root elongation, probably as a result of an inhibition of auxin-induced cell elongation. Also inhibits protien synthesis in root tips.

BROADLEAF WEEDS CONTROLLED:

amaranth		PAFACAA
carpetweed		PADABBA
common lambsquarters	(b)	PBDAEBA
common purslane		PEDADBA
common ragweed	(b)	PBFAEBA
florida pusley		PEMAEBB
groundsel	(b)	PBFCXAA
ladysthumb, smartweed		PEAAGBP
pigweed		PAAAABI
shepherd spurse	(a)	PBKAHBA
wild buckwheat	(b)	PEAAGBH

(a) Use the higher dosages (464-478; 524-152).
(b) Reduces competition through the use of higher dosages when applied immediately after planting (524-331, 524-152, 524-153).

*Propachlor
Ramrod

GRASSES AND OTHER MONOCOTS CONTROLLED:

annual ryegrass		PZAAAAH
barnyardgrass		PCABHBB
broadleaf signalgrass	(b)	PCAARBD
crabgrass		PCABFAA
fall panicum		PCACEBD
giant foxtail		PCACUBA
goosegrass		PCABIBA
green foxtail		PCACUBF
sandbur		PCAAWAA
yellow foxtail		PCACUBD

(b) Reduces competition through the use of higher dosages when applied immediately after planting (524-331, 524-152, 524-153).

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Corn, Field	0.1 ppm (grain) 1.5 ppm (forage)	/28006AA
4-6 (20% G) 4-5 (25% G) 3.94-5.78 (26.25% G) 3.9-5.85 (65% WP) 4.0-6.0 (42% FlC)	Preemergence. Broadcast or band. Apply after planting prior to emergence of crop or weeds. Furrow irrigated corn requires incorporation to a depth of 0.5 to 2 inches. Apply the wettable powder in 20 gallons of water per acre, and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air.	
2-4 (13.34% G) 2.7-4.5 (18% G) 2.41-3.85 (48.1% WP) 3.5-5.5 (31.5% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Do not use on highly organic soils such as peat or muck. Apply the wettable powder in 20 to 40 gallons of water per acre, and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air. Formulated with atrazine.	
0.67-3 (10% G) 1.5-3 (30% WP) 1.46-2.93 (39% WP) 0.69-3 (2 lb/gal EC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Plant seed at least 1.75 inches deep or injury may result. Do not use on sand or loamy sand soils, or on soils with less than 1 percent organic matter. Apply the wettable powder and emulsifiable concentrate in 25 to 40 gallons of water per acre. If initial seeding fails, soybeans (seed crop only), field corn or grain sorghum may be replanted in treated soil. Thoroughly rework soil before replanting. Do not replant other crops within 4 months after application. Formulated with linuron.	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
AGRICULTURAL CROPS	
Corn, Field (continued)	
5.6 (20% G) 5 (25% G) 5.2-5.85 (65% WP) 5.25-6.0 (42% FlC)	Preemergence. Broadcast or band application to lister or deep furrow planted corn. Apply after planting and prior to emergence of crop or weeds. Heavy rain following application will reduce effectiveness on the top and sides of the furrow. Apply the wettable powder in 20 or more gallons of water per acre, and the flowable liquid concentrate in 15 or more gallons of water per acre by ground, and in a minimum of 5 gallons by air.
3.6-4.5 (18% G) 2.41-3.85 (48.1% WP) 3.5-5.5 (31.5% FlC)	Preemergence. Broadcast or band application to lister or deep furrow planted corn. Apply after planting and prior to emergence of crop or weeds. Heavy rain following application will reduce effectiveness on the top and sides of the furrow. Apply the wettable powder in 20-40 gallons of water per acre, and the flowable liquid concentrate in 15 or more gallons of water per acre by ground and in a minimum of 5 gallons by air. Formulated with atrazine.
2.47-3.9 (65% WP) 2.5-4.0 (42% FlC)	Preemergence. Broadcast or band. Tank mix with atrazine. May be applied immediately after planting until weeds or grasses reach the 2-leaf stage. Apply the wettable powder in 20 or more gallons of water per acre, and the flowable liquid concentrate in 15 or more gallons water per acre by ground, and in a minimum of 5 gallons by air.
4.55-5.85 (65% WP)	Early postemergence. Broadcast. Apply before grasses reach the 2-leaf stage.
2.41-3.85 (48.1% WP) 2.5-4.0 (42% FlC)	Early postemergence. Broadcast. Apply before grasses and broadleaf weeds reach the 2-leaf stage. Apply the wettable powder in 20 to 40 gallons of water per acre, and the flowable liquid concentrate in 15 or more gallons water per acre by ground, and in a minimum of 5 gallons by air. Formulated with atrazine (WP) and tank mixed with atrazine (FL/C).

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Corn (hybrid seed crop)	N.F. (seed) 1.5 ppm (forage)	/28005BA
4-6 (20% G) 4-5 (25% G) 3.94-5.78 (26.25% G) 3.9-5.85 (65% WP) 4.0-6.0 (42% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Furrow irrigated corn requires incorporation to a depth of 0.5 to 2 inches. Apply the wettable powder in 20 gallons of water per acre, and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons per acre by air.	
4.75 (8.3% G)	Preemergence. Band application. Apply at planting. Formulated with parathion.	
2.7-4.5 (18% G) 2.41-3.85 (48.1% WP) 3.5-5.5 (31.5% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Do not use on highly organic soils such as peat or muck. Apply the wettable powder in 20 to 40 gallons of water per acre, and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air.	
2.47-3.9 (65% WP) 2.5-4.0 (42% FlC)	Preemergence. Broadcast or band. Tank mix with atrazine. May be applied immediately after planting until weeds or grasses reach the 2-leaf stage. Apply wettable powder in 20 or more gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre and in a minimum of 5 gallons by air.	
5-6 (20% G) 5 (25% G)	Preemergence. Broadcast or band application to lister or deep furrow planted corn. Apply after planting and prior to emergence of crop or weeds. Heavy rain following application will reduce effectiveness on the top and sides of the furrow. Apply the wettable powder in 20 or more gallons of	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Corn (hybrid seed crop) (continued)		
5.2-5.85 (65% WP) 5.25-6.0 (42% FL/C)	water per acre and the flowable liquid concentrate in 15 gallons of water per acre and in a minimum of 5 gallons by air.	
3.6-4.5 (18% G) 2.41-3.85 (48.1% WP) 3.5-5.5 (31.5% FlC)	Preemergence. Broadcast or band application to lister or deep furrow planted corn. Apply after planting and prior to emergence of crop or weeds. Heavy rain following application will reduce effectiveness on the top and sides of the furrow. Apply the wettable powder in 20 to 40 gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre in a minimum of 5 gallons by air. Formulated with atrazine.	
4.55-5.85 (65% WP)	Early postemergence. Broadcast. Apply before grasses reach the 2-leaf stage.	
2.41-3.85 (48.1% WP) 2.5-4.0 (42% FlC)	Early postemergence. Broadcast. Apply before grasses and broadleaf weeds reach the 2-leaf stage. Apply in 20 to 40 gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre in a minimum of 5 gallons by air. Formulated with atrazine (WP) and tank mix with atrazine (FlC).	
Corn, Silage Corn, Sweet	0.1 ppm (grain and fresh corn (kernels plus cobs with husks removed)) 1.5 ppm (forage)	/22005AA /15005AA
4-6 (20% G) 4-5 (25% G) 3.94-5.78 (26.25% G)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Furrow irrigated corn requires incorporation to a depth of 0.5 to 2 inches. Apply the wettable powder in 20 gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air.	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
AGRICULTURAL CROPS	
Corn, Silage cluster (continued)	
3.9-5.85 (65% WP)	
4.0-6.0 (42% FlC)	
2-4 (13.34% G)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Do not use on highly organic soils such as peat or muck. Apply the wettable powder in 20 to 40 gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air. Formulated with atrazine.
2.7-4.5 (18% G)	
2.41-3.85 (48.1% WP)	
3.5-5.5 (31.5% FlC)	
2.47-3.9 (65% WP)	Preemergence. Broadcast or band. Tank mix with atrazine. May be applied immediately after planting until weeds or grasses reach the 2-leaf stage. Apply wettable powder in 20 or more gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air.
2.5-4.0 (42% FlC)	
5-6 (20% G)	Preemergence. Broadcast or band application to lister or deep furrow planted corn. Apply after planting and prior to emergence of crop or weeds. Heavy rain following application will reduce effectiveness on the top and sides of the furrow. Apply the wettable powder in 20 or more gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air.
5.0 (25% G)	
5.2-5.85 (65% WP)	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Corn, Silage cluster (continued)		
5.25-6.0 (42% FlC)		
3.6-4.5 (18% G)	Preemergence. Broadcast or band application to lister or deep furrow planted corn. Apply after planting and prior to emergence of crop or weeds. Heavy rain following application will reduce effectiveness on the top and sides of the furrow. Apply the wettable powder in 20 to 40 gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air. Formulated with atrazine.	
2.41-3.85 (48.1% WP)		
3.5-5.5 (31.5% FlC)		
4.55-5.85 (65% WP)	Early postemergence. Broadcast. Apply before grasses reach the 2-leaf stage.	
2.41-3.85 (48.1% WP)	Early postemergence. Broadcast. Apply before grasses and broadleaf weeds reach the 2-leaf stage. Apply wettable powder in 20 to 40 gallons of water per acre and the flowable liquid concentrate in 15 gallons of water per acre by ground and in a minimum of 5 gallons by air. Formulated with atrazine (WP) and tank mixed with atrazine (FL/C).	
2.5-4.0 (42% FlC)		
Corn, Sweet	See Corn, Silage cluster.	
Cotton	0.1 ppm (cottonseed)	/28007AA
3.94-5.25 (26.25% G)	Preemergence. Apply after planting and prior to emergence of crop or weeds.	
Flax	3.0 ppm (seed) 10.0 ppm (straw)	/28009AA
4.0 (42.0% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Apply in 15 or more gallons of water or liquid fertilizer per acre and in a minimum of 5 gallons by air.	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Peas (green) (for processing only)	0.2 ppm (determined after removing any pod present when marketed) 1.5 ppm (forage)	/15009AA
3.9-4.88 (65% WP) 4.0-5.0 (42% FlC)	Preemergence. Broadcast. Apply after planting and prior to emergence of crop or weeds. Apply wettable powder in 20 or more gallons of water per acre and flowable liquid concentrate in 15 gallons of water per acre. May be applied by air in MN only, using at least 5 gallons of water per acre, no aerial restrictions on flowable liquid concentrate formulation.	
Pumpkins	0.1 ppm (pumpkin)	/10011AA
4.0-6.0 (42.0% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Apply in 15 or more gallons of water per acre and in a minimum of 5 gallons by air. Do not apply to soil with less than 1% organic matter. Apply once per growing season. Do not apply within 90 days of harvest.	
Sorghum (grain crop)	0.25 ppm (grain) 5 ppm (forage) Do not graze or feed forage or silage from treated fields to dairy animals. Do not cut immature plants for silage.	/24006AA
3.94-5.25 (26.25% G) 4-5 (20% G) 3.9-4.88 (65% WP) 4.0-5.0 (42% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Apply the wettable powder in 20 or more gallons of water per acre and the flowable liquid concentrate in 15 gallons or more water per acre and in a minimum of 5 gallons by air.	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
AGRICULTURAL CROPS	
Sorghum (grain crop) (continued)	
4.46-5.25 (26.25% G)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Furrow irrigated corn requires incorporation to a depth of 0.5-2 inches.
4.46-5.25 (26.25% G) 5.0 (42.0% FlC)	Preemergence. Broadcast to lister or deep furrow planted sorghum. Apply after planting and prior to emergence of crop or weeds. Heavy rains following application may reduce effectiveness on top and sides of the furrow. Apply the flowable liquid concentrate in 15 gallons or more water per acre and in a minimum of 5 gallons by air.
3.0-4.0 (42% FlC)	Preemergence. Broadcast. Tank mix with bifenox. Apply after planting but prior to emergence of crop or weeds. Apply in 15 or more gallons of water per acre.
2.93-3.9 (65% WP)	Use limited to all areas except OK and TX. Preemergence. Broadcast. Tank mix with atrazine. Apply after planting until weeds or grasses reach the 2-leaf stage. Apply in 20 or more gallons of water per acre by ground, or in 5 gallons of water by air. Apply in sprayable fluid fertilizer only. Do not use on coarse textured soils with less than 3 percent organic matter.
2.5-4.0 (42% FlC)	No use restrictions except in TX use only on fine textured soils of the Gulf Coast. Preemergence. Broadcast. Tank mix with atrazine. Apply immediately after planting but before emergence of weeds or crop. Apply in 15 or more gallons of water or sprayable fluid fertilizer per acre by ground or in a minimum of 5 gallons water by air. Do not use on coarse textured soils with less than 3 percent organic matter.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
AGRICULTURAL CROPS	
Sorghum (grain crop) (continued)	
2.78-2.93 (65% WP) 2.5-3.0 (42% FlC)	Preemergence. Broadcast or band. Tank mix propazine. Apply after planting and prior to emergence of crop or weeds. Apply wettable powder in 20 gallons of water per acre and the flowable liquid concentrate in 15 or more gallons of water per acre by ground in a minimum of 5 gallons of water by air.
0.69-3.0 (2 lb/gal EC)	Use limited to Great Plains area. Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Plant seed at least 1 inch deep. Do not use on sand or loamy sand soils, or on soils with less than 1 percent organic matter. Apply in 25 to 40 gallons of water per acre. If initial seeding fails, soybeans (seed crop only), field corn or grain sorghum may be replanted in treated soil. Do not retreat during the same crop year. Do not replant other crops within 4 months after application. Formulated with linuron.
2.41-3.85 (48.1% WP)	Use of 48.1% WP prohibited in OK.
3.5-5.5 (31.5% FlC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Do not use on coarse textured soils with less than 3 percent organic matter. In TX, use only on the fine textured soils of the Gulf Coast. Apply wettable powder in 20 to 40 gallons or flowable liquid concentrate in 15 gallons of water or fluid fertilizer by ground and a minimum of 5 gallons by air. Formulated with atrazine.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Soybeans (seed crop)	N.F. (seed) Do not graze or feed forage from treated areas. Do not use seed for food, feed or oil purposes.	/28023BA
3.94-5.25 (26.25% G) 3.9-4.88 (65% WP) 4-5 (20% G) (25% G)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Apply the wettable powder in 20 or more gallons of water per acre.	
0.67-3 (10% G) (2 lb/gal EC)	Preemergence. Broadcast or band. Apply after planting and prior to emergence of crop or weeds. Plant seed at least 1.75 inches deep. Do not use on sand or loamy sand soils, or on soils with less than 1 percent organic matter. Apply the emulsifiable concentrate in 25 to 40 gallons of water per acre. If initial seeding fails, soybeans (seed crop only), field corn, soybeans or grain sorghum may be replanted in treated soil. Do not retreat during the same crop year. Do not replant other crops within 4 months after application. Formulated with linuron.	
AERIAL AND TANK MIX APPLICATIONS		
Aerial Application		9001500
—	Refer to AGRICULTURAL CROPS Corn, Field; Corn (hybrid seed crop); Corn, Silage; Corn, Sweet; Flax; Peas (green) (for processing only); Pumpkins; Sorghum (grain crop).	

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations	
AERIAL AND TANK MIX APPLICATIONS		
Tank Mix		9900300
—	Refer to AGRICULTURAL CROPS Corn, Field; Corn (hybrid seed crop); Corn, Silage; Corn, Sweet; Sorghum (grain crop)	

2-CHLORO-N-ISOPROPYLACETANILIDE

Appendix A

Listing of Registered Pesticide Products by Formulation

93% technical chemical (TC)
  2-chloro-N-isopropylacetanilide (019101)
    000524-00310

8.3% granular (G)
  2-chloro-N-isopropylacetanilide (019101) plus parathion (057501)
    000524-00156

10% Granular (G)
  2-chloro-N-isopropylacetanilide (019101) plus linuron (035506)
    000352-00334   000524-00289

13.34% granular (G)
  2-chloro-N-isopropylacetanilide (019101) plus atrazine (080803)
    000100-00519   000464-00484

18% granular (G)
  2-chloro-N-isopropylacetanilide (019101) plus atrazine (080803)
    000524-00303

20% granular (G)
  2-chloro-N-isopropylacetanilide (019101)
    000464-00478   000524-00152   001258-00784   002749-00149

25% granular (G)
  2-chloro-N-isopropylacetanilide (019101)
    000524-00265

26.25% granular (G)
  2-chloro-N-isopropylacetanilide (019101)
    000524-00280

30% wettable powder (WP)
  2-chloro-N-isopropylacetanilide (019101) plus linuron (035506)
    000524-00288

39% wettable powder (WP)
  2-chloro-N-isopropylacetanilide (019101) plus linuron (035506)
    008461-00003

48.1% wettable powder (WP)
  2-chloro-N-isopropylacetanilide (019101) plus atrazine (080803)
    000100-00513   000524-00286

65% wettable powder (WP)
  2-chloro-N-isopropylacetanilide (019101)
    000464-00477   000524-00153   001258-00785   002749-00161

Appendix A

Listing of Registered Pesticide Products by Formulation (continued)

2 lb/gal emulsifiable concentrate (EC)
  2-chloro-N-isopropylacetanilide (019101) plus linuron (035506)
    000352-00345

31.5% flowable liquid concentrate (FlC)
  2-chloro-N-isopropylacetanilide (019101) plus atrazine (080803)
    000524-00328

42.0% flowable liquid concentrate (FlC)
  2-chloro-N-isopropylacetanilide (019101)
    000524-00331

Appendix B

Listing of Common and Chemical Names Used in This Entry

Chemical Code	Common Name	EPA Acceptable Common/Chemical Name
035506	Linuron	3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea
057501	Parathion	O,O-Diethyl O-P-nitrophenyl phosphorothioate
080803	Atrazine	2-chloro-4-(ethylamino)-6-(isopropylamino)-s-triazine
080808	Propazine	2-chloro-4,6-bis(isopropylamino)-S-triazine
104301	Bifenox	Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate

Appendix C

Listing of Registration Numbers by Site* (Formulation Codes in Appendix A)

AGRICULTURAL CROPS

Corn, Field /28006AA

000100-00513 (WP) 000100-00519 (G) 000352-00334 (G)
000352-00345 (EC) 000464-00477 (WP!) 000464-00478 (G!)
000464-00484 (G) 000524-00152 (G!) 000524-00153 (WP!)
000524-00265 (G!) 000524-00280 (G!) 000524-00286 (WP)
000524-00288 (WP) 000524-00289 (G) 000524-00303 (G)
000524-00328 (F1C) 000524-00331 (F1C!) 001258-00784 (G!)
001258-00785 (WP!) 002749-00149 (G!) 002749-00161 (WP!)
008561-00003 (WP)

Corn (Hubrid seed crop) /28005BA

000100-00513 (WP) 000464-00477 (WP!) 000464-00478 (G!)
000524-00152 (G!) 000524-00153 (WP!) 000524-00156 (G)
000524-00265 (G!) 000524-00280 (G!) 000524-00286 (WP)
000524-00303 (G) 000524-00328 (F1C) 000524-00331 (F1C!)
001258-00784 (G!) 001258-00785 (WP!) 002749-00149 (G!)
002749-00161 (WP!)

Corn, Silage /22005AA

000100-00513 (WP) 000100-00519 (G) 000464-00477 (WP!)
000464-00478 (G!) 000464-00484 (G) 000524-00152 (G!)
000524-00153 (WP!) 000524-00265 (G!) 000524-00280 (G!)
000524-00286 (WP) 000524-00303 (G) 000524-00328 (F1C)
000524-00331 (F1C!) 002749-00149 (G!) 002749-00161 (WP!)

Corn, Sweet /15005AA

000100-00513 (WP) 000100-00519 (G) 000464-00477 (WP!)
000464-00478 (G!) 000464-00484 (G) 000524-00152 (G!)
000524-00153 (WP!) 000524-00265 (G!) 000524-00280 (G!)
000524-00286 (WP) 000524-00303 (G) 000524-00328 (F1C)
000524-00331 (F1C!) 002749-00149 (G!) 002749-00161 (WP!)

Cotton /28007AA

000524-00280 (G!)

Flax /28009AA

000524-00331 (F1C!)

Peas (green) (for processing only) /15009AA

000464-00477 (WP!) 000524-00153 (WP!) 000524-00331 (F1C!)

Pumpkins /10011AA

000524-00331 (F1C!)

* Single active ingredient (S.A.I.) products are identified by !. The rest of the products are multiple active ingredients (M.A.I.).

EPA Index to Pesticide Chemicals

2-CHLORO-N-ISOPROPYLACETANILIDE

Appendix C

Listing of Registration Numbers by Site* (Formulation Codes in Appendix A) (continued)

AGRICULTURAL CROPS

/24006AA

Sorghum (grain crop)

000100-00513 (WP) 000352-00345 (EC) 000464-00477 (WP!)
000464-00478 (G!) 000524-00152 (G!) 000524-00153 (WP!)
000524-00280 (G!) 000524-00286 (WP) 000524-00328 (F1C)
002749-00149 (G!) 002749-00161 (WP!)

Soybeans (seed crop)

000352-00334 (G) 000352-00345 (EC) 000464-00477 (WP!)
000464-00478 (G!) 000524-00152 (G!) 000524-00153 (WP!)
000524-00265 (G!) 000524-00280 (G!) 001258-00784 (G!)
001258-00785 (WP!) 002749-00149 (G!) 002749-00161 (WP!)

* Single active ingredient (S.A.I.) products are identified by !. The rest of the products are multiple active ingredients (M.A.I.)

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-2) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

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[1] Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

[2] The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

OR

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*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Yes	00104354	No
61-2 - Statement of Composition	TGAI	Partially	00104327, 00104354	Yes 2/
61-3 - Discussion of Formation of Ingredients	TGAI	Yes	00104327, 00104354	No
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No	-	Yes 2/
62-2 - Certification of Limits	TGAI	No	-	Yes 2/
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Partially	00104310, 00104327 00104354	Yes 2/
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00104327, 00104354	No
63-3 - Physical State	TGAI	Yes	00104327, 00104354	No
63-4 - Odor	TGAI	Yes	00104327	No
63-5 - Melting Point	TGAI	Yes	00104327, 00104354	No
63-6 - Boiling Point	TGAI	Yes	00104327, 00104354	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00104354	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI	Yes	00104354	No
63- 9 - Vapor Pressure	PAI	Yes	00104354	No
63-10 - Dissociation constant	PAI	Yes	00104354	No
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes 4/
63-12 - pH	TGAI	No	-	Yes 2/
63-13 - Stability	TGAI	Yes	00104354	No
63-20 - Corrosive Characteristics	TGAI	No	-	Yes 2/
Other Requirements:				
64- 1 - Submittal of samples	Choice	N/A 3/		

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

§158.120 Product Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than six months from the receipt date of this guidance package.
3/ N/A= Not required for the purposes of this standard.
4/ Octanol/water partition coefficient data is required by July 1985, because of Agency's concern for possible ground water contamination by propachlor.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	00015670, 00092429 00026613, 00092430 00026614, 00093250	Yes 2/3/
- Livestock	PAIRA and plant metabolites	Partially	00026614, 00026913	Yes 2/4/5/6/
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Partially	00063712, 00104321 00104311, 00105170 00092430, 00093250	Yes 7/
- Animal residues	TGAI and metabolites	Partially	00093251, 00104321 00093252, 00105170	Yes 7/
171-4 - Storage Stability Data	PAI	No	-	Yes 8/
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
° Beets, sugar, roots	TEP	Partially	00092429	Yes 2/9/13/
° Beets, sugar, tops	TEP	Partially	00092429	Yes 2/9/13/
° Corn, forage	TEP	Partially	00093252, 00104237 00093264	Yes 2/9/10/14/15
° Corn, grain	TEP	Partially	00065896, 00104307 00093517,	Yes 2/9/13/16/ 17/18/ 25/

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.125 Residue Chemistry				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
° Corn, sweet	TEP	Partially	00065896, 00104307 00093517,	Yes 2/9/13/16/17/
° Cottonseed	TEP	Partially	00093518, 00104303	Yes 2/9/19/
° Flax, seed	TEP	Partially	00136439, 00136440	Yes 2/9/20/
° Flax, straw	TEP	Partially	00136439, 00136440	Yes 2/9/
° Peas	TEP	Partially	00104312	Yes 2/9/21/
° Peas, forage	TEP	Partially	00104312	Yes 2/9/21/
° Pumpkins	TEP	Partially	00067280	Yes 2/9/22/
° Sorghum, grain	TEP	Partially	00026612,00105170 00028535	Yes 2/9/18/
° Sorghum, fodder	TEP	Partially	00026612, 00105170 00028535	Yes 2/9/
° Sorghum, forage	TEP	Partially	00026612, 00105170 00028535	Yes 2/9/
* Soybeans (for seed)	TEP	No	-	Yes 26/

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
- Potable Water	EP	N/A 24/		
- Fish	EP	N/A.		
- Irrigated Crops	EP	N/A		
-- Field trials	EP	N/A		
-- Processed Food/Feed	EP	Reserved		
- Food Handling	EP	N/A		
- Meat/milk/poultry/eggs				
° Cattle	TGAI	Partially	00093251, 00093264	Yes 2/10/12/
° Milk	TGAI	No	-	Yes 2/10/12/
° Goats	TGAI	No	-	Yes 2/10/
° Hogs	TGAI	No	-	Yes 2/10/
° Horses	TGAI	No	-	Yes 2/10/
° Sheep	TGAI	Partially	00026916	Yes 2/10/23/
° Poultry	TGAI	Partially	00026920	Yes 2/11/
° Eggs	TGAI	Partially	00026920	Yes 2/11/

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2/ Data must be submitted no later than two years from the receipt date of this guidance package.
3/ ^{14}C ring labeled data with corn and sorghum up to the seed stage are required.
4/ ^{14}C ring labeled data on the nature of the residue in ruminants are required.
5/ Data on the metabolism of propachlor in poultry is required.
6/ Data on the metabolism of propachlor in non-ruminants (swine) will be required if rat metabolism data is is significantly different from the goat or chicken metabolism data.
7/ A radiocarbon study in which samples are analyzed simultaneously by cold and hot analytical methodology for the N-isopropylaniline moiety including a comparison of the results are required. If other metabolites are found in or on plants and in animals, then an enforcement method to determine these residues would be required.
8/ Data on the storage stability of propachlor residues in plant and animal samples are required.
9/ Residue data on the metabolites of propachlor in plants are required.
10/ When the residue data gaps have been filled, the registrant should propose a tolerance for residues in or on corn fodder.
11/ An additional poultry feeding study on metabolites of propachlor in poultry and eggs will be required if additional metabolites of concern are found in the poultry metabolism study.
12/ A cow feeding study on propachlor and its metabolites is required. [Previous IBT data invalidated/OGC]
13/ Geographical representation of residue data are not adequate, therefore, additional field residue data are required. The registrant should consult the Agency for appropriate geographical areas for residue data.
14/ Residue data on corn forage are required to support the application rate of 6 lb ai/A on soils with an organic matter content of more than 3%.
15/ Additional residue data for corn fodder using the 20% granular formulation are required.
16/ Residue data for corn grain using the 20% granular and 42% flowable liquid formulations are required.
17/ Residue data for sweet corn using the flowable liquid concentrate (FlC) are required.
18/ Residue data for the oil and milling fractions from the processing of treated corn or sorghum grain are required.
19/ Residue data in cotton forage are required. An acceptable alternative would be a restriction against the grazing of livestock on cotton forage.
20/ Residue data in flax seed hulls which are fed to livestock are required.
21/ Residue data for peas using the flowable liquid concentrate are required.
22/ Residue data for pumpkins using the 90-day pre harvest or post harvest interval (PHI) are required.
23/ The feeding rate in the sheep study must be clarified.
24/ N/A= Not applicable for the purposes of this standard.
25/ Delete the interpretation as a non-food use, of applications made to hybrid corn grown for seed.
26/ Delete the interpretation as a non-food use, of applications made to soybeans grown for seed.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No	-	Yes 4/
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No	-	Yes 5/
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes 6/
161-4 - In Air	TGAI or PAIRA	A	N/A 3/		
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	Partially 11/	00087854	Yes 7/
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00087854	No
162-3 - Anaerobic Aquatic	TGAI or PAIRA		N/A 3/		
162-4 - Aerobic Aquatic	TGAI or PAIRA		N/A 3/		
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	Partially	00087854 05016652	Yes 8/12/
163-2 - Volatility (Lab)	TEP		N/A 3/		
163-3 - Volatility (Field)	TEP		N/A 3/		

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No	-	Yes 6/
164-2 - Aquatic (Sediment)	TEP		N/A 3/		
164-3 - Forestry	TEP		N/A 3/		
164-4 - Combination and Tank Mixes	TEP		N/A 3/		
164-5 - Soil, Long-term	TEP	A	N/A 3/		
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes 7/
165-2 - Rotational Crops (Field)	TEP	A	13/		
165-3 - Irrigated Crops	TEP		14/		
165-4 - In Fish	TGAI or PAIRA	A,B	No	-	Yes 3/13/
165-5 - In Aquatic Non-Target Organisms	TEP		N/A 3/		
§ Subpart K- Reentry (158.140)	TEP		N/A 3/		

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ N/A= Not applicable for purposes of this standard.
4/ A hydrolysis/degradation study is required by July, 1985.
5/ A photodegradation study in water is required by July, 1985.
6/ A photodegradation study on soil is required by July, 1985.
7/ An additional metabolism test in aerobic soil is required by July, 1986.
8/ Additional data on mobility of degradates from aged propachlor are required by April, 1985.
9/ Soil dissipation data are required by July, 1987.
10/ Data must be submitted no later than two years from the receipt date of this guidance package.
11/ Study must be for one year or until patterns of degradate formation and decline are established.
12/ The aged leaching study did not specify aging conditions or soil temperature and moisture content. Additional data are required on mobility of degradates from aged propachlor.
13/ Data required only if significant residues of concern are detected in the confined accumulation study.
14/ Reclaimed irrigation water not used for crops.
15/ A flow-through test is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B	Yes	00104350	No
81-2 - Acute Dermal Toxicity	TGAI	A,B	Yes	00104351	No
81-3 - Acute Inhalation Toxicity Rat	TGAI	A,B	No	-	Yes 3/6/
81-4 - Primary Eye Irritation	TGAI	A,B	Yes	00104352	No 19/
81-5 - Primary Skin Irritation	TGAI	A,B	Yes	00104353	No
81-6 - Dermal Sensitization	TGAI	A,B	No	-	Yes 4/7/21/
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A,B	N/A 20/		
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B	Partially	00093270	Yes 4/10/
82-2 - 21-Day Dermal	TGAI	A,B	N/A 20/		
82-3 - 90-Day Dermal	TGAI	A,B	No	-	Yes 4/8/
82-4 - 90-Day Inhalation - Rat	TGAI	A,B	No	-	Yes 4/9/
82-5 - 90-Day Neurotoxicity - Hen/Mammal	TGAI	A,B	N/A 20/		

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rat Dog	TGAI	A,B	No	-	yes 11/12/
83-2 - Oncogenicity Study - 2 species: Rat and Mouse	TGAI	A,B	No	-	Yes 11/13/
83-3 - Teratogenicity - 2 species: Rat and Rabbit	TGAI	A,B	Partially	00115136	Yes 14/22/
83-4 - Reproduction, 2-generation	TGAI	A,B	No	-	Yes 11/15/
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B	No	-	Yes 16/
84-2 - Chromosomal Aberration	TGAI	A,B	No	-	Yes 16/
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	No	-	Yes 16/

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B	Partially	00026913	Yes 4/17/
85-2 - Domestic Animal Safety	Choice		No		Yes 5/18/
85-3 - Dermal Absorption Study			N/A 20/		

TABLE A
GENERIC DATA REQUIREMENTS FOR ALACHLOR

§158.135 Toxicology
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than six months from the receipt date of this guidance package.
4/ Data must be submitted no later than one year from the receipt date of this guidance package.
5/ Data must be submitted no later than two years from the receipt date of this guidance package.
6/ An acute inhalation toxicity study in the rat is required.
7/ A dermal sensitization study in the rabbit is required.
8/ A 90-day dermal study in the rabbit is required.
9/ A 90-day inhalation study in the rat is required.
10/ A 90-day feeding study in rodent, and non-rodent is required.
11/ The Agency will require interim reports on the chronic studies. (The registrant should consult the Agency to determine the interim reporting dates for the chronic toxicity studies).
12/ A chronic toxicity study in rat and in dog is required by June 1987.
13/ An oncogenicity study in rat and in mouse is required by January 1987.
14/ A teratology study in the rabbit is required by July 1985.
15/ A two generation reproduction study in the rat is required by January 1987.
16/ The following mutagenicity data are required by January 1987:
  a. In vitro mammalian cell point mutation [L5178Y (TK), or CHO (HGPRT), or V79 (HGPRT)] tests,
  b. In vitro cytogenetic damage: both chromosomal aberration and SCE (in CHO cells, or human lymphocytes, or other rodent/human cell lines/strains tests,
  c. In vitro/in vivo primary hepatocyte repair for UDS testing both in vivo and in vitro exposure of cells to Alachlor,
  d. In vivo cytogenetics test for chromosomal aberrations using bone marrow preparations of rats,
  e. Dominant lethal test in rats or mice.
17/ Additional protocol data for the general metabolism study in mammals are required.
18/ A domestic animal safety study is required. (The registrant should consult the Agency to determine what toxicology data are required).
19/ Corrosive to the eyes, additional data is not necessary.
20/ N/A= Not applicable for the purposes of this guidance package.
21/ A dermal sensitization study in guinea pigs (Acc. 255806, December 1984) has been received by the Agency and it is being reviewed.
22/ A teratology study in rabbits (Acc. 255758, November 1984) has been received by the Agency and it is being reviewed.

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	1/ Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	Yes	00132907	No
71-2 - Acute Avian Dietary Toxicity					
a) Upland gamebird	TGAI	A,B	Yes	00132908	No
b) Waterfowl	TGAI	A,B	Yes	00134006	No
71-3 - Wild Mammal Toxicity	TGAI	A,B	N/A 7/		
71-4 - Avian Reproduction	TGAI	A,B	N/A 7/		
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B	N/A 7/		
AQUATIC ORGANISM TESTING					
72-1 - Acute Freshwater Fish Toxicity					
a) Warmwater	TGAI	A,B	Yes	00104337 3/ GS0177-0001	No
b) Coldwater	TGAI	A,B	Yes	00041335	No
c) Warmwater	TEP	A,B	Yes	00041338 3/ GS0177-0001	No
d) Coldwater	TEP	A,B	Partially	00041337 3/	Yes 4/

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.145 Wildlife and Aquatic Organisms (continued)					
72-2 - Acute Freshwater Invertebrate Toxicity	TGAI	A,B	Yes	00041336 GS0177-0001	No
	TEP	A,B	Yes	00041339 3/ GS0177-0001	No
72-3 - Acute Toxicity Estuarine and Marine Organisms	TGAI	A,B	Reserved 5/		
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A,B	Reserved 4/		
72-5 - Fish - Life-Cycle	TGAI	A,B	Reserved 4/		
72-6 - Aquatic Organism Accumulation	TGAI	A,B	Reserved 4/		
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B	Reserved 4/		

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact toxicity	TGAI	A,B	Yes	00028772	No
141-2 - Honey bee - toxicity of residues on foliage	TEP		No		No 8/
141-4 - Honey bee subacute feeding study	[Reserved] 6/				
141-5 - Field testing for pollinators	TEP		No		No 8/

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)6/				
142-2 - Aquatic insect life-cycle study	(Reserved)6/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)6/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)6/				

TABLE A
GENERIC DATA REQUIREMENTS FOR PROPACHLOR

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ This study must be combined with other studies to fulfill the guideline requirements.

4/ [Reserved] Requirement reserved pending receipt and review of environmental fate data.

5/ [Reserved] Requirement reserved pending receipt and review of environmental fate data (crops grown in coastal counties on excess of 300,000 acres).

6/ [Reserved] Pending decision as to whether data requirement should be established.

7/ N/A = Not applicable for the purposes of this standard.

8/ No data required because of low acute contact toxicity.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPACHLOR

Data Requirement	1/ Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Yes	00104354	No
61-2 - Statement of Composition	TGAI	Partially	00104327, 00104354	Yes 2/
61-3 - Discussion of Formation of Ingredients	TGAI	Yes	00104327, 00104354	No
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	No	-	Yes 2/
62-2 - Certification of Limits	TGAI	No	-	Yes 2/
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Partially	00104310, 00104327 00104354	Yes 2/
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00104327, 00104354	No
63-3 - Physical State	TGAI	Yes	00104327, 00104354	No
63-4 - Odor	TGAI	Yes	00104327	No
63-5 - Melting Point	TGAI	Yes	00104327, 00104354	No
63-6 - Boiling Point	TGAI	Yes	00104327, 00104354	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00104354	No

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPACHLOR

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	MP	N/A 4/		
63- 9 - Vapor Pressure	MP	N/A 4/		
63-10 - Dissociation constant	MP	N/A 4/		
63-11 - Octanol/water partition coefficient	MP	No		Yes 3/
63-12 - pH	MP	No	-	Yes 2/
63-13 - Stability	MP	N/A 4/	-	
63-14 - Oxidizing or Reducing Action	MP	No	-	Yes 2/
63-15 - Flammability	MP	No	-	Yes 2/
63-16 - Explodability	MP	No	-	Yes 2/
63-17 - Storage Stability	MP	No	-	Yes 2/
63-18 - Viscosity	MP	N/A 4/	-	
63-19 - Miscibility	MP	N/A 4/	-	
63-20 - Corrosive Characteristics	MP	No	-	Yes 2/
Other Requirements:				
64- 1 - Submittal of samples	Choice	N/A 4/		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPACHLOR

§158.120 Product Chemistry
(continued)

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted six months from the receipt of this guidance package.

3/ Octanol/water partition coefficient data is required by July 1985, because of Agency's concern for possible ground water contamination by propachlor.

4/ N/A= Not applicable for the purposes of this standard.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPACHLOR

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00104350	No
81-2 - Acute Dermal Toxicity	MP	Yes	00104351	No
81-3 - Acute Inhalation Toxicity Rat	MP	No	-	Yes 2/4/
81-4 - Primary Eye Irritation	MP	Yes	00104352	No 6/
81-5 - Primary Skin Irritation	MP	Yes	00104353	No
81-6 - Dermal Sensitization	MP	No	-	Yes 3/5/
81-7 - Acute Delayed Neurotoxicity - Hen	MP	N/A 7/		

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PROPACHLOR

§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than six months from the receipt of this guidance package.
3/ Data must be submitted no later than one year from the receipt date of this guidance package.
4/ An acute inhalation toxicity study in the rat is required.
5/ A dermal sensitization study in the rabbit is required.
6/ Corrosive to the eyes, additional data is not necessary.
7/ N/A= Not applicable for the purposes of this standard.

IV. SUBMISSION OF REVISED LABELING INFORMATION

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section and/or Section I, EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is require on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses to be restricted, based either on a previous classification determination made through the optional procedures of 40 CFR 162.30 or based on data already available to the Agency, or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you wish to propose that your product should not be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

1. All Uses Restricted - Pesticide products bearing directions for use for formulations or uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

a. The statement "RESTRICTED USE PESTICIDE," must appear at the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR 162.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some But Not all Uses Restricted - If the Regulatory Position and Rationale states that some uses are classified for restricted use and some uses are unclassified, several courses of action are available:

a. You may label the product for restricted use. If you do so, you may include those uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one containing only unrestricted uses, and the other restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Robert Taylor
Product Manager
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1800

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section II (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

   e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager.

Guide to Use of This Bibliography

1. Content of Bibliography: This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. The bibliography is divided into two sections: (1) citations that contributed information useful to the review of the chemical and that are considered to be part of the data base supporting registrations under the Standard, and (2) citations examined and judged to be inappropriate for use in developing the Standard. This second part of the bibliography exists in the Agency's files and does not accompany this Standard. Interested parties may request a copy from the Agency. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry: The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries: The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by an eight-character temporary identifier. This is also to be used whenever specific reference is needed.

4. Form of the Entry: In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow;

    a. Author: Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency had shown the first known submitter as author.

b. Document Date: When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title: This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses: For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date: Immediately following the word 'received' appears the date of the earliest known submission.

   (2) Administrative Number: The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter: The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification: The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second 123456-B; the 26th, 123456-Z; and the 27th 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Propachlor Standard

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OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.______________ Guidance Document for______________________

Date______________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID#	 Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27953, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by

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any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible, within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five~~

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

APPENDIX IV-2 (continued)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30.	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
  (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid